REMARKS

Claims 20-23 and 56-79 are pending and stand variously rejected under 35 U.S.C. §§ 112, first and second paragraphs. In addition, all claims stand rejected as allegedly anticipated and/or obvious under 35 U.S.C. §§ 102(b) and 103(a).

Claims 20 and 56 have been amended herein to make explicit what was previously implicit, namely that the antibody binds to HCV asialoglycoproteins and does not bind to other HCV proteins. *See, e.g.,* page 15, lines 2-4. No new matter has been added as a result of these amendments and entry thereof is respectfully requested. The amendments are made to expedite prosecution and are not made for reasons related to patentability.

In view of the following remarks and foregoing amendments, Applicants respectfully request reconsideration of the application.

35 U.S.C. 112, Second Paragraph

All pending claims were rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph. (Office Action, page 2). In particular, the recitation that the antibody is "directed against" was alleged to be indefinite. (Office Action, page 3).

Without conceding the correctness of the Examiner's position (and indeed Applicants submit that the term "directed against" is more than sufficiently definite), independent claims 20 and 56 have been amended herein to indicate that the antibody binds to a particular protein. Accordingly, this rejection has been obviated and Applicants respectfully request withdrawal thereof.

35 U.S.C. 112, First Paragraph, Enablement

Claims 20-23 and 56-79 stand rejected as allegedly not enabled by the specification as filed. (Office Action, pages 3-4). In support of this rejection, it is maintained that the specification does not reasonably provide enablement for making an antibody for the stated antigen. (Office Action, page 4). In addition, it is alleged that the indefiniteness of the term "directed against" renders is impossible to know when the antibody of the invention has been made. (Office Action, page 4).

Applicants traverse the rejection and supporting remarks.

The foregoing amendments obviate the rejection based on alleged indefiniteness of the term "directed against." In this regard, the claims now recite that the claimed antibodies bind to HCV asialoglycoprotein and not to other HCV proteins. Accordingly, one of skill in the art

could readily ascertain whether a particular antibody generated using standard techniques falls within the scope of the claims.

Turning to the Examiner's assertion that the specification does not enable a skilled artisan to make antibodies, Applicants submit that this is legally and factually incorrect. It is axiomatic that the specification need not disclose (and preferably omits) what is well known to those of skill in the art. For years, the Federal Circuit has acknowledged that making antibodies and testing their binding characteristics is utterly routine to those of skill in the field. *See, e.g., In re Wands,* 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 231 USPQ 81, 94 (Fed. Cir. 1986), *cert denied,* 480 U.S. 947 (1987). Cases such as *Wands* and *Hybritech* establish that both production of antibodies and screening methods to identify characteristics of antibodies (including binding characteristics) were well known by the mid to late 1980's -- years before the 1990 filing date of the pending application. Accordingly, undue experimentation is not required to make and test antibodies as claimed and the specification enables the claims throughout their scope.

Furthermore, whenever the PTO makes such a rejection for failure to teach and/or use the invention, the PTO must explain its reasons for the rejection and support the rejection with (i) acceptable evidence, or (ii) reasoning which contradicts the applicant's claim: the reasoning must be supported by current literature as a whole and the PTO must prove the disclosure requires undue experimentation. *In re Marzocchi,* 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971). The Examiner has provided no support for the arguments presented in the current rejection and, as such, Applicants submit that the rejection should be withdrawn.

In sum, given the high level of skill in the art and routine nature of each step of the antibody-making and antibody-screening procedures, it would not require undue experimentation to make and test antibodies as of Applicants' filing date. Accordingly, the specification fully enables the pending claims and withdrawal of this rejection is respectfully requested.

35 U.S.C. 112, First Paragraph, Written Description

Claims 20-23 and 56-79 stand rejected as allegedly not described in the specification as filed in such a way as to reasonably convey to the skilled artisan that applicants were in possession of the claimed invention. (Office Action, pages 4-5). In support of this rejection, the Office maintains that the fact that Applicants contemplated antibodies does not mean they were in possession of the invention and, in addition, that the specification does not provide any details that allow one of skill in the art to know that the antibody of the invention has been made or that

the contemplation defines an antibody that is different than disclosed by Houghton. (Office Action, pages 5-6).

Applicants traverse the rejection and supporting remarks.

The fundamental factual inquiry in written description is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. Determining whether the written description requirement is satisfied is a question of fact and the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim,* 191 USPQ 90 (CCPA 1976). It is not necessary that the application describe the claimed invention *in ipsis verba.* Rather, all that is required is that the specification reasonably convey possession of the invention. *See, e.g., In re Lukach,* 169 USPQ 795, 796 (CCPA 1971). Finally, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange,* 209 USPQ 288 (CCPA 1981).

Furthermore, the Patent Office's own guidelines on written description are clear -- the written description requirement is highly fact-dependent and there is a strong presumption that an adequate written description of the claimed invention is present at the time of filing:

> [t]he description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is a product or a process. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. (Final Examiner Guidelines on Written Description, 66 Fed. Reg. 1099, emphasis added).

Simply put, there is absolutely **no** requirement that Applicants exemplify (or reduce to practice) antibodies falling within the scope of the claims in order to adequately describe the pending claims. Rather, the test is whether the specification and state of the art contains sufficient disclosure regarding the claimed antibodies to satisfy the written description requirement. In the pending case, the routine and conventional nature of making antibodies

establishes that the specification as filed more than adequately describes and details characteristics of the claimed antibodies.

Applicants further note at the outset of this discussion that it is well accepted that original claims constitute their own description. *See, e.g.,* M.P.E.P. § 2163; *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980); *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); and *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the pending case, original claims 20 to 23 were directed to assay kits for detecting the presence of HCV asialoglycoproteins using antibodies specific to these proteins. Accordingly, it is clear that Applicants were in possession of the presently claimed subject matter at the time their application was filed and that they adequately described the pending claims in their original disclosure.

Furthermore, because any written description inquiry must begin with claim construction, it is important to note at the outset of this discussion that the claims clearly recite both the structure (antibodies) and the function (specific binding to HCV asialoglycoproteins) of the recited antibodies. Therefore, when properly construed, it is plain that only antibodies having the recited binding characteristics are encompassed by the pending claims. Furthermore, it is clear from the specification as filed that the written description requirement is met with respect the claimed molecules.

As noted above, it is axiomatic that the specification need only describe in detail that which is new or not conventional. (See, Guidelines on Written Description, page 275). In the case at hand, a skilled artisan reading the specification would have known that Applicants were in possession of claimed antibodies as recited in the claims in view of the extensive knowledge regarding making antibodies and screening antibodies.

Applicants also direct attention to the Applicants also direct the Examiner's attention to Example 16 of the Office's "Synopsis of Application of Written Description Guidelines," (hereinafter referred to as "PTO Example 16") which provides still further evidence that the specification adequately describes the claimed antibodies. Indeed, PTO Example 16 clearly establishes that claims directed to antibodies that bind to novel antigens are described:

> **Specification:**
> The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach, in an example, antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge

in the art is such that antibodies are structurally well characterized. ... It is also well known that antibodies can be made against virtually any protein.

Claim:
An isolated antibody capable of binding to antigen X.

Analysis:
A review of the full contact of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced. ...

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X was implicitly disclosed as a result of isolation of antigen X.

Conclusion: The disclosure meets the requirements of 35 U.S.C. § 112, first paragraph as providing adequate written description for the claimed invention.

The specification, claim, analysis and conclusion set forth in PTO Example 16 are directly relevant and highly analogous to the written description analysis in the pending case. In particular, PTO Example 16 makes clear that the specification need not contain examples of particular antibodies, because the structural characteristics of all antibodies is well defined and the technology well developed. Like the applicant PTO Example 16, Applicants in the pending case teach purification and characterization of the antigen (HCV asialoglycprotein). However, considering the routine nature of making antibodies to well characterized proteins, PTO Example 16 makes it plain that one of skill in the art would have recognized the spectrum of antibodies encompassed by the pending claims.

In view of disclosure of the specification, state of the art and original claims, it would have been plain to the skilled artisan that Applicants' were in possession of the claimed invention at the time the specification was filed. Accordingly, withdrawal of this rejection is respectfully requested.

35 U.S.C. §§ 102/103

Claims 20-23 and 56-79 stand rejected as allegedly anticipated by or, in the alternative, obvious under 35 U.S.C. § 103(a) by EP 0 318 216 (hereinafter "Houghton"). It is alleged that Houghton inherently discloses an isolated antibody that is reactive with asialoglycoproteins of HCV E1 and/or E2. (Office Action, pages 6-7, citing Section IV.I.2 on page 56 of Houghton).

The cited reference does not specifically describe antibodies that bind to HCV asialoglycoproteins, as claimed. Rather, Houghton screens for anti-HCV antibodies using the HCV c100-3 antigen, which encompasses epitopes from the NS4 protein of HCV, not from E1 and/or E2. Accordingly, withdrawal of the rejections is requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §1.16, §1.17, and §1.21, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648, referencing Atty. Docket No. 2302-0154.01.

Please direct all further written communications regarding this application to:

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